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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/725,994

12/03/2003

Rakha Hari Das

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/725,994

Applicant(s)

DAS ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3May2004, 13October2004, 6February2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13October2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' Preliminary Amendment, received 3 May 2004, is acknowledged. Claims 1-17 have been amended. New claim 18 has been added.
2. Applicants' Second Preliminary Amendment, received 13 October 2004, is acknowledged.
3. Applicants' Third Preliminary Amendment, received 6 February 2006, is acknowledged. New claims 19 has been added.
4. Claims 1-19 are pending and under consideration.

Specification

5. The disclosure is objected to because of the following informalities:

Throughout the entire application a procedure is named as "Touch down", "touch down" or "Touch Down". Please make sure that the procedure name is the same all through the specification.

Page 1, line 18, "Organisation" should be "Organization"; line 19, delete "reports", replace "is" with "are"; lines 20, 24, 25, reference citations are incomplete, please provide source and pages; line 29-30, "mycobacterium tuberculosis" should be "*Mycobacterium tuberculosis*", delete "other", replace "of" with "other".

Page 2, line 9, "problem" should be "problems"; line 14, "Although staining" should be "Staining"; line 17, delete period immediately following "case", reference citation is incomplete, please provide source and pages; line 21, "organism" should be "organisms"; line 28, reference citations are incomplete, please provide source and pages; line 29, "M. tuberculosis" should be "*M. tuberculosis*".

Page 3, lines 2, 10, 12, 13, 24, and 27 reference citations are incomplete, please provide source and pages; line 25, "M. tuberculosis" should be "*M. tuberculosis*".

Page 4, lines 2, 23, and 26, reference citations are incomplete, please provide source and pages; line 2, "M. bovis-BCG" should be "*M. bovis*-BCG".

Page 5, line 14, what is a "sea change"; lines 24-25, "mycobacterium avium-intracellare" should be "*Mycobacterium avium-intracellulare*"; line 29, "upto" should be "up to", "Pulmonary" should be "pulmonary"; line 30, "*M.kansassi*" should be "*M.kansasii*".

Page 6, sentence in lines 8-10 has no verb; line 14, replace "is" with "are"; line 26, delete the " after the word Test, reference citations are incomplete, please provide source and pages; line 27, "M. tuberculosis" should be "*M. tuberculosis*".

Page 7, line 25, reference citation is are incomplete, please provide source and pages.

Page 8, line 17, "invention lies" should be "invention lie"; line 37, "italisized" should be "italicized".

Page 9, line 3, "*M.kansassi*" should be "*M.kansasii*"; line 26, "step" should be "steps"; line 34, "method claims" should be "methods claim"; line 36, "culture but they" should be "culture, they".

Page 10, line 2, "result amplification" should be "result in amplification"; line 9, "ensure" should be "ensures"; line 12, "steps" should be "step"; line 13, "Sputum" should be "sputum"; line 15, "reaction. The" should be "reaction, the"; line 18, "proteins thus results" should be "proteins resulting"; line 19, "ensure" should be "ensures"; lines 23 and 26, reference citations are incomplete, please provide source and pages.

Page 11, line 2, what is meant by "leading to through lysis"?; lines 3 and 19, reference citations are incomplete, please provide source and pages; line 9, "accomplish" should be "accomplishes", "help" should be "helps"; line 13, "Phenol being an extremely"

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should be "phenol being extremely".

Page 12, lines 1 and 3, "fig 1" should be "Fig. 1"; line 10, "sequence ID number3" should be "SEQ ID NO:3"; line 12, "sequence ID number 4" should be "SEQ ID NO:4"; line 13, "fig2" should be "Fig. 2"; line 25, "resulted amplification" should be "resulted in amplification".

Page 13, line 2, "*M.kansass*" should be "*M.kansasii*"; lines 9 and 11, reference citations are incomplete, please provide source and pages; line 12, "results into" should be "result in".

Page 14, line 11, "need" should be "needs"; line 33, "table 2, (figures" should be "Table 2, (Figures"; line 34, "(figures 4, fig 5" should be "(Figure 4, Fig. 5,"

Page 15, line 1, "fig 6" should be "Fig. 6"; line 2, what are the units of "167"?/ line 23, "fig:7" should be "Fig. 7", "programme" should be "program".

Page 16, line 17, "Smear" should be "smear"; Lines 19-20, the sentence has no verb; line 20, "Acid" should be "acid"; line 23, "these specimen" should be "these specimens".

Page 17, line 20, "primers of designed" should be "primers designed"; line 23, "analysing" should be "analyzing".

Page 19, line 17, what is "constions"?

Page 21, line 4, "do not need" should be "does not need"; line 12, what is meant by "Whole was used for PCR."?; line 15, "Area" should be "area".

Page 22, line 2, "Oligonucleotide" should be "oligonucleotide"; lines 14, 15, 17, 23, and 25, the sequences should be listed as "SEQ ID NO:xxx; line 31, what is meant by "duplicate second"?

Page 23, lines 1-4, neither of the two sentences has a verb; line 16, what is meant by

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"above than"?

Page 24, line 1, "Gel" should be "Gels"; line 23, "method is this do" should be "method is that it does"; line 23, insert "as" between "amplification" and "this".

Page 26, there are checkmarks on the left side of the sequence, delete the checkmarks.

Appropriate correction is required.

Drawings

6. M.P.E.P. §2422.02, third paragraph, recites that "the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings."

Neither Figure 2 nor its Brief Description contains the required SEQ ID NO. Appropriate correction is required.

7. Figure 3 is objected to under 37 CFR 1.83(a) because it fails to show any details, i.e., the figure is totally black, as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement

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Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

8. Claim 1 is objected to because of the following informalities: line 2, "comprising steps of" should be "comprising the steps of"; line 1 of step g, "analysing" should be "analyzing".

Appropriate correction is required.

9. Claim 4 is objected to because of the following informality: line 5, "specimens from centrifugation" should be "specimens by centrifugation". Appropriate correction is required.

10. Claim 7 is objected to because of the following informality: line 3, "Sacroc syl" should be "Sarcosyl". Appropriate correction is required.

11. Claim 16 is objected to because of the following informality: line 3, "fro" should be "for". Appropriate correction is required.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 1, it is unclear what is meant by "clarifying the clinical specimens from containment" in step a. The language of steps d and e are unclear. In step d, what is meant by "designing sequence of SEQ ID NO. 4"? What is meant by "said designed sequence comprising of selected"? In step e, is the set of specific primers actually SEQ ID NO:5 and SEQ ID NO:6 or are they "primers of SEQ ID NO.5" and "primers of SEQ IN NO. 6"? It is unclear what methods are being utilized in step g "for a quick assessment of HIV co-infection".

Claims 2-16 and 18 depend from claim 1, but do not clarify the issues.

14. Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Both claims recite a decontamination mix containing mild alkali, NaOH, tri sodium citrate and a mucolytic agent and guanidinium isothiocyanate in the range of about 0.4-2.5 M or 0.5-2.0M. It is unclear if the ranges are referring only to the guanidinium isothiocyanate concentration or the total mix, or each individual component of the mix.

15. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a kit comprising primers selected from the group consisting of SEQ ID NO:5 and SEQ ID NO:6.

It is unclear from the claim language, i.e., "comprising primers" (denoting more than 1 primer), if the kit contains both SEQ ID NO:5 and SEQ ID NO:6, or multiple copies of one or the other SEQ ID NO.

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16. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to "A set of primer 'of' SEQ ID NO.5 and 6 comprising". It is unclear from the claim language if the set of primers consists of SEQ ID NO:5 and SEQ ID NO:6 or if the primers are for detecting SEQ ID NO:5 and SEQ ID NO:6.

Conclusion

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "Rodney P. Swartz". The signature is fluid and cursive, with the first name "Rodney" and last name "Swartz" clearly distinguishable.

RODNEY P. SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

September 2, 2006